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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,618	06/10/2002	Herath Mudiyanselage Athula Chandrasiri Herath	2543-1-008/PCT US	8602

7590 07/12/2005

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EXAMINER	
LYLES, JOHNALYN D	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,618	CHANDRASIRI HERATH ET AL.	
	Examiner	Art Unit	
	Johnalyn Lyles	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-15* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 14 in part, drawn to a method of screening for and/or diagnosis of a neuropsychiatric and/or neurological condition in a subject by **detecting a polypeptide**, classified in class 435, subclass 7.1 or 69.7.

II. Claims 4 and 15, drawn to a method for phrophylaxis and/or treatment of a neuropsychiatric and/or neurological condition in a subject by **administering a polypeptide**, classified in class 514, subclass 2.

III. Claim 5 and 14 in part, drawn to a method of screening for and/or diagnosis of a neuropsychiatric and/or neurological condition in a subject by **detecting a nucleic acid**, classified in class 435, subclass 6.

IV. Claim 6 and 14 in part, drawn to a method for phrophylaxis and/or treatment of a neuropsychiatric and/or neurological condition in a subject by **administering a nucleic acid**, classified in class 514, subclass 44.

V. Claims 7-10 and 14 in part, drawn to a method for phrophylaxis and/or treatment of a neuropsychiatric and/or neurological condition in a subject by **administering an antibody**, classified in class 424, subclass 130.1 or 178.1.

VI. Claim 11, drawn to a pharmaceutical formulation comprising a polypeptide, a nucleic acid, or an antibody, classified in class 514, subclass 2 or 44 or classified in class 424, subclass 130.1.

VII. Claim 12, drawn to a method of screening for compounds that modulate the expression of a polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 13 and 14 in part, drawn to a method for monitoring/assessing breast cancer treatment in a patient, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V, VII, and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are not disclosed as capable of use together and have different functions or effects. Group I and III are methods of **screening for and/or diagnosis** of a neuropsychiatric and/or neurological condition in a subject **by detecting** a polypeptide or a nucleic acid, respectively. Group II, IV, and V are methods **for phrophylaxis and/or treatment** of a neuropsychiatric and/or neurological condition in a subject **by administering** a polypeptide, a nucleic acid, or an antibody, respectively. Group VII is a method of **screening for compounds that modulate the expression** of a polypeptide. Group VIII is a method **for monitoring/assessing breast cancer treatment** in a patient.

Inventions I, III, VII, and VIII and Invention VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the product of Group VI is not disclosed as capable of use with the different methods of Groups I, III, VII, and VIII and has different a different function. The pharmaceutical formulation is used **for prophylaxis and/or treatment** of a neuropsychiatric and/or neurological condition. The methods are **for screening and/or diagnosis** of a neuropsychiatric and/or neurological condition and/or **monitoring/assessing** breast cancer by detecting a polypeptide, nucleic acid, or antibody.

Inventions II, IV, and V and Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the methods for using the pharmaceutical formulations can be practiced with any of the pharmaceutical formulations claimed, including a pharmaceutical formulation with the polypeptide, nucleic acid, or antibody or with a therapeutically effective amount of the polypeptide, nucleic acid, or antibody as claimed.

The inventions of Groups I-VIII are different inventions that have different functions, reagents and/or effect different patient populations. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search required

for one group is not coextensive and required for any of the other groups, restriction for examination purposes as indicated is proper.

Further Restriction Groups

Further election is **required** with the restriction as set forth in the following Groups (A-C). If applicant elects the invention of Groups I-VIII, Applicant must further elect the polypeptide, nucleic acid or antibody. **For Applicant to be fully responsive** to the restriction requirement, the component must be identified for the elected invention.

If Applicant elects **Invention VI**, the select the component of the pharmaceutical formulation from groups A-C below. If Applicant elects **Invention I or II,** then select the polypeptide from group A as set for the below. If Applicant elects **Invention III or IV** then select the nucleic acid from group B as set for the below. If Applicant elects **Invention V, VII, or VIII**, then select the antibody from group C as set for the below.

A. the polypeptide of Figure 1 or Figure 3

B. the nucleic acid of Figure 2, or

C. an antibody that binds the polypeptide of Figure 1 or Figure 3

The inventions include claims to different products and claims directed to numerous nucleic acids, polypeptides, or antibodies. Each product represents a structural and functionally distinct entity. The search and consideration of more than a single product is not coextensive and constitutes an undue search burden on the office, given the ever-increasing size of the databases. Because these inventions are distinct

for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and/or classification, and the search required for one group is not coextensive and required for any of the other groups, restriction for examination purposes as indicated is proper.

Applicant is advised that **a reply to this requirement must include an identification of an amino acid, nucleic acid sequence, or antibody** that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. The Examiner notes that **this is not a species election requirement**; rather it sets forth additional invention groups.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a neuropsychiatric and/or neurological conditions including bipolar affected depression, schizophrenia, and vascular dementia.

Applicant is required under 35 U.S.C. 121 to **elect a single disclosed species** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. **Currently, claims 1-10 and 14-15 are generic.**

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Johnalyn Lyles** whose telephone number is **571-272-3433**. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

SHARON TURNER, PH.D.
PRIMARY EXAMINER
7-11-05